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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/612,285 | 07/03/2003 | Richard Derek Iggo | 604-689 | 5824 |
| 23117 | 7590 | 11/06/2006 | EXAMINER | |
| NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | PRIEBE, SCOTT DAVID | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|---|------------------------------------|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | Application No. 10/612,285 | Applicant(s) IGGO ET AL. | |
| | Examiner Scott D. Priebe, Ph.D. | Art Unit 1633 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 08 September 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☒ They raise the issue of new matter (see NOTE below);
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1-11, 21-23 and 25.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☒ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. ☒ Other: See Continuation Sheet.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit: 1633

Continuation of 3. NOTE: Proposed claim 1 raises new issues under 35 USC 112, 2nd para. The proposed limitation that the binding sites are "inserted as substitutions for all or part of the wild type E1A transcription factor binding site" is indefinite, E1A is a transcription factor, but it does not bind DNA. If "the wild type E1A transcription factor binding site" was intended to mean "the" transcription factor binding site upstream of E1A, then the limitation lacks antecedent basis, and as shown in Fig. 1A there are multiple such binding sites upstream of the E1A transcribed region in the E1A minimal promoter, E1A enhancer, and 5' ITR. Also, additional limitations have been added without proper punctuation (lines 15-17), and the previous improper punctuation is not corrected. With the proposed amendments to claim 1, claim 4 would be either new matter, i.e. a second packaging signal, or an improper dependent claim since proposed claim 1 already requires relocation of the packaging signal to a specific location, rather than the general location recited in claim 4, and as a result claim 4 would be indefinite.

Continuation of 11. does NOT place the application in condition for allowance because: Most of the arguments are based upon the proposed amendment. Since the amendment has not been entered, these arguments are moot. With respect to the rejection over Iggo, Appellant argues that Iggo limits the early genes whose promoter may be altered to those of the E2 region, arguing that "mechanistically directly involved in viral construct nucleic acid replication" excludes E1A. Iggo, page 8, lines 3-8, teaches that the region whose promoter is altered "may be" the region encoding the polymerase, etc. Since expression of the E1A region is required for activation of the genes encoding the polymerase etc., it is mechanistically directly involved in replicating the viral genome. Also, one explicitly described alternative is modification of the E1B promoter alone, or with additional modifications to the E2 or E1A promoters. The instant claims do not exclude modification of both the E1A and E1B promoters, as suggested in Iggo, page 13.

Continuation of 13. Other: Appellant indicates that an amendment of claim 21 was proposed (Reply, page 8), but there is no proposed amendment to claim 21.